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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,560	08/16/2006	Klaus Abraham-Fuchs	32860-001073/US	8514

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EXAMINER	
FUELLING, MICHAEL	

ART UNIT	PAPER NUMBER
4135	

MAIL DATE	DELIVERY MODE
07/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,560	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	MICHAEL FUELLING	4135	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/16/2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is a non-final, first office action on the merits for Application Number 10/589,560 filed August 16, 2006.
2. Claims 1-20 currently are pending and have been examined.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on August 26, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. The foreign reference was crossed out and not considered because an English translation was not provided by the applicant.

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings contain words which are not in English. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

5. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper.

   In applicant's claim for priority, applicant attempts to incorporate foreign patents by reference.

   Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material

previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

   Applicant asserts that the claim elements “memory means”, “input means” and “reading means” are means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim elements are a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. If applicant wishes to have the claim limitations treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

   (a) Amend the claim to include the phrase “means for” or “step for” in accordance with these guidelines: the phrase “means for” or “step for” must be modified by functional language and the phrase must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

   (b) Show that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-6 and 11-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is not directed to a "process" under 35 U.S.C. §101.

In order for a method to be considered a "process" under 35 U.S.C. §101, a claimed process must either: (1) be tied to a particular machine or apparatus or (2) transform a particular article to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584,588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008). If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. §101 and is non-statutory subject matter.

There are two corollaries to these requirements. First, the use of the specific machine or transformation of the article must impose meaningful limits on the claim's scope to impart patent-eligibility. *See Benson*, 409 U.S. at 71-72. Second the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity. *See Flook*, 437 U.S. at 590.

Claim 1 is not sufficiently tied to a particular machine or apparatus, nor does the claimed method transform a particular article to a different state or thing. Claims 2-6 and 11-14 which depend upon claim 1 do not cure the deficiencies of claim 1 and are therefore rejected for the same reasons set forth above.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brimm et al., US Patent Number 5,072,383 (Brimm).

Referring to claim 1, Brimm discloses: *storing at least one of study-related and patient-related data* (Abstract patient information system)*, to be read out by a non-study doctor* (Abstract physician) *assigned to the patient, in a memory* (C4, L24 "memory unit") *during the clinical study* (C4, L10-20 "automated clinical records management").

Referring to claim 2, Brimm discloses all of the limitations of claim 1 and further discloses: *the data are* [sic] *stored in the memory by a study doctor* (C9, L17 physician enters orders).

Referring to claim 3, Brimm discloses all of the limitations of claim 1 and further discloses: *the non-study doctor reads the data out from the memory before an interaction with the patient* (C5, L53).

Referring to claim 4, Brimm discloses all of the limitations of claim 1 and further discloses: *the data are* [sic] *stored in the memory with standardized structuring* (Fig. 10).

Referring to claim 5, Brimm discloses all of the limitations of claim 1 and further discloses: *clear instructions to the non-study doctor are stored as data* (C11, L25 creation of task list).

Referring to claim 6, Brimm discloses all of the limitations of claim 1 and further discloses: *the data are* [sic] *assigned to various classes, and the non-study doctor reads only information of one class out from the memory* (C9, L19 select from a list the type of information).

Referring to claim 7, Brimm discloses:

- *a memory* (C4, L24 "memory unit") *assigned to the patient for at least one of study-related and patient-related data* (Abstract patient information system)

- *a data input device* (**11** bedside workstation) *for storing data in the memory*

- *a data reading device* (C4, L25 terminal unit with display means)*, accessible by a non-study doctor* (Abstract physician) *assigned to the patient, for reading the data out from the memory*

Referring to claim 8, Brimm discloses all of the limitations of claim 7 and further discloses: *the memory is portable* (C6, L52 discs).

Referring to claim 9, Brimm discloses all of the limitations of claim 7 and further discloses: *the memory is part of a data network* (C5, L64 network)*, to which data input and output devices are connectable* (C6, L18 monitoring equipment) *and wherein authorization, is required for access to the data* (C9, L13 entry to the system restricted by security measures).

Referring to claim 10, Brimm discloses all of the limitations of claim 7 and further discloses: *the data reading device is portable* (**11** bedside workstation).

Referring to claim 11, Brimm discloses all of the limitations of claim 2 and further discloses: *the non-study doctor reads the data out from the memory before an interaction with the patient* (see claim 3 details above).

Referring to claim 12, Brimm discloses all of the limitations of claim 2 and further discloses: *the data are stored in the memory with standardized structuring* (see claim 4 details above).

Referring to claim 13, Brimm discloses all of the limitations of claim 2 and further discloses: *clear instructions to the non-study doctor are stored as data* (see claim 5 details above).

Referring to claim 14, Brimm discloses all of the limitations of claim 2 and further discloses: *the data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory* (see claim 6 details above).

Referring to claim 15, Brimm discloses all of the limitations of claim 8 as detailed above and further discloses: *the data reading device is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 16, Brimm discloses all of the limitations of claim 9 as detailed above and further discloses: *the data reading device is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 17, Brimm discloses:

- memory means (C4, L24 “memory unit”)*, assigned to the patient, for at least one of study-related and patient-related data* (Abstract patient information system)*;*

- input means for storing data in the memory means (**11** bedside workstation)*; and*

- reading means (C4, L25 terminal unit with display means)*, accessible by a non-study doctor assigned to the patient* (Abstract physician)*, for reading the data out from the memory means.*

Referring to claim 18, Brimm discloses all of the limitations of claim 17 as detailed above and further discloses: *the memory means is portable* 9 (C6, L52 discs).

Referring to claim 19, Brimm discloses all of the limitations of claim 17 as detailed above and further discloses: *the memory means is part of a data network* (C5, L64 network)*, to which data input and output devices are connectable* (C6, L18 monitoring equipment) *and wherein authorization is required for access to the data* (C9, L13 entry to the system restricted by security measures).

Referring to claim 20, Brimm discloses all of the limitations of claim 17 as detailed above and further discloses: *the reading means is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Conclusion

12. The pertinent art made of record and not relied upon includes:

- Dempsey et al., US Patent Number 5,417,222 which discloses a portable patient monitoring device and method.

- Collen, Morris F., M.D., "Clinical Research Databases--A Historical Review", 1990, Journal of Medical Systems, Vol. 14, No. 6.

13. Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Michael Fuelling** whose telephone number is **571.270.1367**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, **NAEEM HAQ** can be reached at **571.272.6758**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

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or faxed to **571-273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

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/Michael Fuelling/

Examiner

July 7, 2009

Art Unit 4135

/Naeem Haq/

Supervisory Patent Examiner, Art Unit 4135